PATENT

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Applicant : Frank W. Cunningham, M.D.
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Title: **PUNCTURE AND CUT RESISTANT SURGICAL GLOVE WITH MACROSPHERE CAPTURE DEVICES**
Examiner : Samuel A. Acquah
Art Unit : 1711

DECLARATION -- RULE 1.132

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Sir:

I, Frank W. Cunningham, M.D. have more than 14 years of experience in the design and development of flexible puncture resistant and puncture proof materials. I am a orthopedic surgeon and have been researching this area for many years due to my concern for protecting doctors and nurses during surgery from accidental needle punctures, which might transmit dangerous diseases such as AIDS. As a result of my research in this field I hold multiple patents in the field, and I am a person skilled in the state of the art.

I have been engaged in a search for an optimal material, which would have all of the desired properties of a standard surgical glove, and also, as well, have puncture and cut resistance. My testing included a great variety of materials and methods. In the area of composites, I have tested the use of a hard filler distributed uniformly in an elastomer. The testing showed a proportionate increase in stiffness, and decreased elasticity, with increase in the density and aggregate thickness of the composite material, to achieve adequate puncture resistance. Thus making the resultant composite unacceptably

stiff for the purpose of a surgical glove. This led to my invention described in U.S. Patent No. 5,601,895 issued on February 11, 1997 to Frank W. Cunningham. In that invention, very small steel discs, with small perforations, provided excellent puncture resistance, by means of a positive needle-stopping mechanism, however only fair flexibility. It did, however, establish the effectiveness of the "capture" mechanism.

In the present invention, I invented a spherical form of capture mechanism. It is important to note that round spherical particles by themselves have no capture mechanism. As described in the present patent application, the microspheres are aggregated to form a larger sphere, the macrosphere, which has capture mechanisms over the entire surface of the macrosphere. These substantially spherical macrospheres, with a smooth, non-stick surface, greatly enhance the flexibility of the material, which makes it suitable for surgical gloves.

It is my expert opinion that the present invention is not obvious in view of Oakley (USPN 6,080,474) entitled "Polymeric Articles Having Improved Cut Resistance".

Oakley teaches:

"A polymeric article having improved cut-resistance composed of (A) an initial polymeric article having cut-resistant properties; and (B) a cut-resistant elastomeric coating disposed on an outer surface of the initial polymeric article, wherein the elastomeric coating is composed of an elastomer and a hard filler distributed in the elastomer."

Oakley in column 4 teaches:

"The hard filler particles may be in the form of flat particles (i.e., platelets), elongated particles (i.e., needles), irregularly-shaped particles, or round particles. Preferably, the hard filler particles are in the form of platelets because platelets are more efficient in imparting cut-resistance.

The particle size of the hard filler particles preferably ranges from about 1 to about 5 microns. For flat or elongated particles, the particle size refers to the

length along the long axis of the particle (i.e. the long dimension of an elongated particle or the average diameter of the face of a platelet).

The hard filler distributed in the elastomer polymer is preferably a metal or metal alloy, a ceramic material or a crystalline mineral. Suitable metals include, e.g., tungsten, copper, brass, bronze, aluminum, steel, iron, monel, cobalt, titanium, magnesium, silver, molybdenum, tin and zinc. Non-limiting examples of suitable crystalline minerals include baddeleyite, chloritoid, clinozoisite, chondrodite, euclasite, petalite, sapphire, spodumene, staurolite, and clay. Suitable ceramic materials include, e.g., glass and alumina. Most preferably, the hard filler used in the elastomeric coating of this invention is alumina."

Clearly Oakley teaches a hard filler ("round particles") distributed in an elastomer polymer coating. The "round particles" are preferably alumina.

The Examiner's position is that the filler material of Oakley, specifically the "round particles" of Oakley distributed in the elastomer polymeric coating makes obvious the macrospheres of the present invention.

Oakley throughout never teaches any specific structure of the particulate material, that would suggest the organization of the particulate material into any fixed form such as an aggregate of microspheres to form a macrosphere. Microspheres in the present invention are spherical particles that are components of macrospheres that themselves are substantially spherical. Multiple microspheres are bound together to form macrospheres. Macrospheres cannot and do not form themselves spontaneously out of a "soup" of "round particles" distributed in an elastomer polymer coating.

In fact, Oakley teaches distributing the "round particles" in the elastomer polymer coating, which teaches away from the present invention. Oakley is simply a mixture formed en mass, "to provide a uniform distribution of the filler in the

elastomer" (Oakley col. 4 lines 63-64).

If the microspheres of the present invention are taken to be analogous to the "round particles" of Oakley, then the microspheres of the present invention according to Oakley should be distributed in the elastomer polymer coating. However, in the present invention the microspheres are not distributed throughout the elastomer polymer coating, but are instead aggregated into specific structures to make macrospheres, which have a specific structure, as taught in FIGs. 8 and 9 of the present invention.

As described in the present invention microspheres are formed in a special machine such as a "Spherisator", at a temperature of 2,000 F (for alumina). (See FIG. 12 of the present invention, and page 17 lines 2 to 20.) Once formed, the microspheres are then used to fabricate macrospheres by the same special machine, the "Spheristator". The macrospheres are formed from microspheres blended with polyethylene, which is essentially a non-elastic polymer, at temperature of about 500 F. (See FIG. 13 of the present invention, and page 17 line 21 to page 18 line 5, and page 18 lines 6 to 18.) When the macrospheres cool and the microspheres aggregate, the resulting macrospheres are substantially spherical aggregates of the microspheres and the polymer, as shown in FIG. 8. This structure of the macrospheres is inventive and is certainly not obvious in view of Oakley, which teaches no structure, but instead teaches a distribution of the round particles in the elastomer media.

Whether or not the Oakley distribution of the "round particles" in the elastomer media provides a puncture resistant property is not the issue. The Oakley material may or may not be puncture resistant. The claims of the present invention are to the specific structure of a macrosphere. This structure of the present invention is not obvious in view of the Oakley teachings.

Again, the present invention teaches a specific microstructure, which is an aggregate of microspheres forming a macrosphere, as described in FIGs. 4-11, page 14 line 5, to page 17 line 1. FIGs. 8 to 11 and page 15 line 7 to page 17 line 1, describe the macrosphere's "capture mechanism", which is a result

of its specific microstructure. There is a positive puncture resistance and needle-stopping action when the needle enters and is captured by a macrosphere. Once a needle point is "captured" by a macrosphere, the sharp point is blunted by the macrosphere attached to it, which prevents the needle from passing through.

Oakley also does not teach coated porous macrospheres nor the specific methods of forming macrospheres in the present invention.

In my more than 14 years of experience in the design and development of flexible puncture resistant and puncture proof materials, puncture resistance has stood out as a long standing problem. I believe the present invention, which is the structure of the macrosphere, provides a solution to this long standing problem. As described in the patent application, protecting medical personnel from injuries from needle sticks is of paramount importance in an age of life threatening diseases such as AIDS.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Frank W. Cunningham, M.D. — 10/22/05
Date

I hereby certify that this paper or fee is being deposited with the United States Postal Service as first class mail under 37 CFR §1.8(c) in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 10/22/2005
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Lee W. Tower — 10/22/2005
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